(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the Part D sponsor to a third party for similar services during each of the previous 2 years.

(2) *Aggregate compensation.* (i) An entity must not provide aggregate compensation to its agents or brokers greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan at any time.

(ii) An agent or broker must not receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type at any time.

(iii) The initial compensation is paid for replacements between unlike plan types.

(3) *Compensation payment and payment recovery.* (i) Compensation may only be paid for the enrollee's months of enrollment during a plan year.

(ii)(A) Subject to paragraph (b)(3)(iii) of this section, compensation payments may be made at one time for the entire current plan year or in installments throughout the year.

(B) Compensation may not be paid until January 1 of the enrollment year and, if paid at all, must be paid in full by December 31 of the enrollment year.

(iii) When a beneficiary disenrolls from an MA plan, compensation paid to agents and brokers must be recovered for those months of the plan year for which the beneficiary is not enrolled. For disenrollments occurring within the first 3 months, the entire compensation must be recovered unless CMS determines that recoupment is not in the best interests of the Medicare program.

(4) *Compensation structure.* (i) A Part D sponsor must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(ii) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(c) It must ensure that all agents selling Medicare products are trained annually, through a CMS endorsed or approved training program or as specified by CMS, on Medicare rules and regulations specific to the plan products they intend to sell.

(d) It must ensure agents selling Medicare products are tested annually by CMS endorsed or approved training program or as specified by CMS.

(e) Upon CMS' request, the organization must provide to CMS, in a form consistent with current CMS guidance, the information necessary for it to conduct oversight of marketing activities.

(f) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(g) Plan sponsor must report annually, as directed by CMS the following:

(1) Whether it intends to use independent agents or brokers or both in the upcoming plan year.

(2) If applicable, the specific amount or range of amounts independent agents or brokers or both will be paid.

(h) Finder's (referral) fees. Finder's (referral) fees paid to all agents and brokers—

(1) May not exceed an amount that CMS determines could reasonably be expected to provide financial incentive for an agent or broker to recommend or enroll a beneficiary into a plan that is not the most appropriate to meet his or her needs; and

(2) Must be included in the total compensation not to exceed the fair market value for that calendar year.

[73 FR 54253, Sept. 18, 2008, as amended at 73 FR 67413, Nov. 14, 2008; 76 FR 21577, Apr. 15, 2011; 76 FR 54635, Sept. 1, 2011; 77 FR 22171, Apr. 12, 2012; 79 FR 29966, May 23, 2014]

§ 423.2276 Employer group retiree marketing.

Part D sponsors may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits

through the Part D sponsor, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

Subpart W—Medicare Coverage Gap Discount Program

SOURCE: 77 FR 22172, Apr. 12, 2012, unless otherwise noted.

§ 423.2300 Scope.

This subpart implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements regarding the following:

(a) Condition for coverage of applicable drugs under Part D.

(b) The Medicare Coverage Gap Discount Program Agreement.

(c) Coverage gap discount payment processes for Part D sponsors.

(d) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(e) Manufacturer audit and dispute resolution processes.

(f) Resolution of beneficiary disputes involving coverage gap discounts.

(g) Compliance monitoring and civil money penalties.

(h) The termination of the Discount Program Agreement.

§ 423.2305 Definitions.

As used in this subpart, unless otherwise specified—

Applicable discount means 50 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

Date of dispensing means the date of service.

Labeler code means the first segment of the Food and Drug Administration national drug code (NDC) that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Medicare Coverage Gap Discount Program (or Discount Program) means the Medicare coverage gap discount program established under section1860D–14A of the Act.

Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) means the agreement described in section 1860D–14A(b) of the Act.

Medicare Part D discount information means the information sent from CMS or the TPA to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on prescription drug events as determined by CMS.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size and type.

Negotiated price for purposes of the Discount Program, means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and